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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,978	04/13/2001	Matthew D. Phaneuf	01948/073002	6288
21559	7590	10/20/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			BUTTNER, DAVID J	
			ART UNIT	PAPER NUMBER
			1712	
DATE MAILED: 10/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,978

Applicant(s)

PHANEUF ET AL.

Examiner

David Buttner

Art Unit

1712

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 16-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Applicant's election without traverse of Group I claims 1-15 in the reply filed on 9/7/04 is acknowledged.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear if the claimed conditions relate to (1) the method of bonding the compound to the polymer OR (2) an after treating step that the composition must be exposed to OR (3) a test in which composition must be capable of passing. If the later, than "is" should be replaced by "will remain" and "if exposed to" should replace "in". The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-15 rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The Yuan thesis describes "dyeing" acid functional polyurethanes with Ciprofloxacin. This is applicant's preferred material and must inherently meet applicant's limitations. The thesis was presented to at least some of the applicants at least as early as 1998. This shows the "derivation" required (MPEP 2137).

Claims 1-15 rejected under 35 U.S.C. 102(a and b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Yuan thesis.

Yuan describes, "dyeing" acid functional polyurethane with ciprofloxacin. This is applicant's preferred material and must inherently meet applicant's limitations.

The front page of the thesis gives the date as 1998 which would render the reference a 102 (b) type rejection. Applicant's 1449 form lists 1999 as the publication date. This would qualify the thesis as a 102 (a) or 102 (b) type reference depending on the specific month and day. Applicant should provide the specific date the thesis was published/made publicly available/orally presented in the next response.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Santerre '115 Patent.

Santerre covalently bonds pharmacological compounds such as ciprofloxacin into a polyurethane (abstract). Breaking of the covalent bonds releases the active ingredient (col. 7 line 24).

The material is useful as wound dressings etc (col. 1 line 58). Inherently, the material is expected to meet applicant's tests (claim 6-8) because ciprofloxacin covalently bonded to polyurethane is applicant's preferred material.

This ciprofloxacin – urethane polymer can be used as a coating on acid functional polyurethane objects (col. 11 line 20-29). This coating can form covalent bonds to the substrate (col. 11 line 27).

Claims 1-10, 13 and 15 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Leveen '755 patent.

Leveen suggest wound dressings of a polymer reversibly complexed with iodine (abstract) or chlorhexidine gluconate (col. 8 line 1). The reversible binding permits release of therapeutic iodine (col. 5 line 15).

Claims 1-8, 10, 13 and 14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Leveen '380 Patent.

Leveen complexes iodine with a polyurethane for catheters (abstract). the complexed iodine is slowly dissociable (col. 5 line 32).

Claims 1-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Ito '662 Patent.

Ito adheres dyes or antibiotics to a base material (abstract). The antibiotic can be ciprofloxacin (col. 3 line 6). The base can be polyurethane (col 3 line 31). Although

Ito terms adherence "more or less permanently" (col. 3 line 42), any bond can be broken under the proper conditions. Furthermore, in view of the fact Ito names applicant's preferred antibiotic and substrate, the adherence must inherently be reversible.

Claims 1-10, 13 and 14 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Reich '523 Patent.

Reich produces functionalized polyurethanes for medical articles (abstract). The polyurethane can be reacted with an antibiotic (col. 16 line 16). This active agent will release at a controlled rate (col. 16 line 55).

Claims 1-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Pudleiner AU 199745537 patent.

Pudleiner polymerizes a polyurethane in the presence of an active substance such as ciprofloxacin (page 6 line 25). The active substance bonds to the urethane matrix (page 7 line 5). The bond can be considered "reversible" because any chemical bond be broken under the appropriate conditions.

Claims 1-8 and 13-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Phaneuf article in Journal of Biomaterials Applications vol. 12.

Phaneuf produces polyurethanes for catheters, wound dressings etc (page 101). The urethane includes anchor sites for bining later added materials (page 103), Anticoagulants etc (page 115) can be bound through the anchor site. The bond can be

considered reversible because any chemical bond can be broken under the right conditions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Buttner whose telephone number is (571) 272-1084. The examiner can normally be reached on Weekdays from 10:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID J. BUTTNER
PRIMARY EXAMINER

D. Buttner/af
October 8, 2004

